objective of this study was to assess the characteristics of the reviews performed by the PMPRB in the period of 1998 to 2014. **METHODS:** Data for all reviews performed by the PMPRB in the period 1998 to 2014 were derived from the PMPRB webpage. Descriptive analysis, and trend analysis were conducted. **RESULTS:** PMPRB reviewed a total of 1457 formulations/strengths corresponding to 689 active ingredients and combinations in the study period. Seventy percent of PMPRB prices were within the guidelines and accepted. Two percent of the prices exceeded the guidelines but did not trigger the criteria for commencing an investigation; however, the patentee is expected to decrease the price. Three percent of the National Average Transaction Price exceeded the Maximum Average Potential Price, which triggered the investigation criteria and the drug was reported "Under Investigation". Four percent of the drug prices investigated were not excessive. One and half percent of the drug prices were considered excessive, and by getting to this conclusion two percent of patentees submitted a Voluntary Compliance Undertaking (VCU). Finally one and half percent of patentees did not submit a VCU and PMPRB decided that a patented medicine was sold at an excessive price in any market in Canada, and the PMPRB issued a Notice of Hearing. Drug prices that were within guidelines ranged from92.6% (2001 to 2004) to 95.2% (2005 to 2009) respectively. However, it decreased to 69.8%in 2010-2014. **CONCLUSIONS:** The majority of the reviews performed by the PMPRB concluded that the prices were not excessive.

PHP21

CHANGES OF THE HUNGARIAN HEALTH INSURANCE PHARMACEUTICAL BUDGET BETWEEN 2007-2013

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OBJECTIVES: At the end of 2006, there was an important reform in the Hungarian pharmaceutical market, including serious changes in the health insurance reimbursement of medicines. The aim of our study is to analyze the changes in the Hungarian health insurance pharmaceutical budget between 2007-2013. **METHODS:** Data were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. We analyzed the changes of the health insurance pharmaceutical budget between 2007-2013. Results are given in Hungarian Forint (HUF) and US dollars (USD). The annual average currency exchange rates were applied according to the data of the Central Bank of Hungary. **RESULTS:** The Hungarian pharmaceutical budget was 323.6 (2007), 325.7 (2008), 343.2 (2009), 357.2 (2010), 376.9 (2011), 315.1 (2012) and 280.0 (2013) billion HUF. The average annual exchange rate between Hungarian Forint and US dollar was 183.83 (2007), 171.80 (2008), 202.26 (2009), 208.15 (2010), 200.94 (2011), 225.37 (2012) and 223.70 (2013), which means that Hungarian Forint significantly weakened compared to USD. After the changes in currency exchange rate, the Hungarian pharmaceutical budget measured by US dollars was 1.76 (2007), 1.90 (2008), 1.70 (2009), 1.72 (2010), 1.88 (2011), 1.40 (2012) and 1.25 (2013) billion USD. The decrease of pharma reimbursement budget from 2011 to 2013 was more significant in USD dollar (33.3 %) than in Hungarian Forint (25.7 %) due to the weakened Hungarian currency. **CONCLUSIONS:** Due to the reform of the whole Hungarian pharmaceutical market, the Hungarian health insurance pharmaceutical budget significantly changed between 2007-2013. This change was more remarkable in USD as the Hungarian currency weakened compared USD during the world economic crisis.

PHP22

EFFECT OF THE U.S.-PERU FREE TRADE AGREEMENT ON PERUVIAN NEW DRUG POLICIES AND THE REGISTRATION OF PHARMACEUTICAL PRODUCTS

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OBJECTIVES: One controversial issue surrounding the Free Trade Agreement (FTA) is patent protection and access to medicines. The FTA necessitated changes in Peruvian legislation to meet requirements of the treaty. This study evaluated the impact of the FTA on number of brand and generic pharmaceuticals registered before and after the agreement and implementation of the new legislation of 2009. **METHODS:** Data from 2005 to 2013 were extracted from the database provided by the Peruvian drug regulatory authority, DIGEMID. The frequency and proportion of brand and generic products registered for the first time at DIGEMID were determined using the variable 'authorization date of first registration'. Re-registered products were determined using the 'authorization and expiration date' of registration. Products awaiting registration were determined by the variable 'status of application'. Chi-square was used to assess differences in proportions. **RESULTS:** A total of 30,201 pharmaceutical and 913 biologics products with a unique registration number were evaluated. The proportion of new registrations was 74% (n=1789) for brand and 26% (n=621) for generic products in 2005; and 80% (n=455) for brand and 20% (n=114) for generic products in 2013 with a decrease of 1,841 (76%) products after legislation. The proportion of re-registrations was 66% (n=714) for brand and 34% (n=361) for generic products in 2005 with the same proportions in 2013 but different frequencies (58 brand and 30 generic) with a decrease of 987 (92%) products after legislation. There were statistically significant differences between brand and generic products before and after the legislation. The proportion of awaiting registrations was 3 times greater for brand than for generic products from 2009 to 2013. **CONCLUSIONS:** Registration of brand products was greater than generic products before and after the FTA and new legislation. The frequency of new registrations and re-registrations decreased after 2009 but increased for products awaiting registration.

PHP23

THE CHARACTERISTICS OF PHARMACY AND THERAPEUTIC COMMITTEES IN SAUDI HOSPITALS

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OBJECTIVES: The Pharmacy and Therapeutics Committee (P&TC) is a policy recommending and enforcing body which oversees the adoption of effective formulary system within the health care organization, the aim of the study is to explore the characteristics of P& TC in tertiary and secondary hospitals in Riyadh city, Saudi Arabia. **METHODS:** A cross-sectional survey targeted hospital pharmacy mangers in Riyadh city in 2014. The survey gathered information about P&TC organizational, communicational and functional characteristics. **RESULTS:** Of 30 hospital pharmacies, 23 (76.6%) pharmacy managers responded, 21(70%) hospitals met the inclusion criteria, 15 (71.4%) are governmental and 6 (28.6%) are private hospitals. Of 21 hospitals, 20 (95.2%) have P&T Committee. 15 (71.4%) committees have all required written policies and procedures that govern the committee business. The average total number of the P&T committee members is 13.5 (SD=5), and dominated by physicians, pharmacists, and nurses (6.9 (SD=3.4), 2.7(SD=1.2), and 1.4(SD=0.8)) respectively. 89.5% of these committees are chaired by physicians and 100% of them are coordinated by the pharmacists. Only 9 (45%) of the committees distribute the meeting agenda to their members 6 days or more before the meeting date. The average number of meetings is 12 (SD=6) meeting per year, drug availability, formulary change updates, drug safety related issues were frequently discussed in each meeting of 11(55%) hospital P&T committees. Formulary non adherence is less frequently, and prescribing guidelines is the least frequent. The average number of drugs deleted or added to the formulary are 6.3(SD=5.9), 19.2 (SD=18.9) drug per year, respectively. **CONCLUSIONS:** Adopting P&T Committee in Saudi governmental hospitals is a common practice, however, it considered in early stage in private hospitals and more likely to be contributed to the accreditation requirements, therefore, more study to be done to study the quality of the committees in private hospital to ensure the effectiveness of formulary system.

PHP24

PRINCIPLES OF POLICY FRAMEWORK IN THE PHARMACEUTICAL WHOLESALE AND RETAIL SYSTEM IN LOWER INCOME EUROPEAN COUNTRIES

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OBJECTIVES: To determine the influencing factors and main principles of regulatory and policy framework in the pharmaceutical wholesale and retail system to identify good practices for adaptation in Central Eastern European (CEE) countries. **METHODS:** A comprehensive literature review in the scientific and grey literature and a series of expert interviews were conducted to identify influencing factors in three major categories: general political, business economic and health policy principles. **RESULTS:** Regulatory and policy framework related to the pharmaceutical wholesale and retail system is influenced by multiple stakeholders with different interest. Health policy demands timely access to high quality medicines to maximise health gain for the population with respect to equity. Budget constraints necessitate public need for a sustainable and efficient pharmaceutical distribution channel. To overcome these constraints, pharmaceutical wholesalers and pharmacies have to improve operational efficiency by taking into account economies of scale/scope; or positive synergies of horizontal and vertical integration. According to general political objectives policy makers may choose from 1) regulated vs. liberalised system, 2) with monopolistic vs. competing wholesalers and community pharmacies 3) with national vs. international, and 4) public vs. private ownership. Pharmacists may consider the provision of advanced health care services besides the traditional logistic activities to intensify professional influence on health policies. **CONCLUSIONS:** Evidence base of policy and regulatory framework related to pharmaceutical trade can be improved based on comprehensive review of scientific evidence on major principles to harmonise different objectives of stakeholders. However, publications with relevance to CEE and in general lower income countries are very limited.

PHP25

ORPHAN AND ULTRA-ORPHAN TECHNOLOGIES IN THE NEW ERA OF PAYMENT REFORM: UNITED STATES PAYER PERCEPTIONS

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OBJECTIVES: To understand United States (US) payer perceptions and challenges in the evaluation of emerging health technologies with orphan and ultra-orphan designations. **METHODS:** In-depth, qualitative, one-on-one interviews were conducted with US payer decision makers from the RTI Health Solutions US Commercial Payer Advisory Panel. **RESULTS:** In the US, patient access to orphan and ultra-orphan technologies is seldom denied due to the rarity of the diseases, unmet needs, and lack of alternative treatments. Payers identify the biggest challenges as lack of clinical and comparative efficacy data and pressures from advocacy groups, patients, and prescribers to fund the ever-increasing numbers of orphan and ultra-orphan technologies, which are often very expensive and have limited clinical evidence. Payers estimated that spending for orphan and ultra-orphan technologies will increase significantly in the next 5 years, leading to concerns over future funding and budgets. Payers were interested in data that could have an impact on costs, cost offsets, resource utilization, readmissions, and real-world outcomes in their settings and patient/member populations. Payers wanted to see better-defined patient populations and unmet needs accompanied by well-defined treatment courses (e.g., when to stop treatment). Benefits of new technologies may not be captured in traditional health economic analyses, thus increasing uncertainty. Bridging the clinical evidence with other robust data will be critical, because payers will be passing on more risk to patients and prescribers in an effort to manage budget constraints. **CONCLUSIONS:** Payers are seeking more value-based information to better inform decision making in the evaluation of new orphan and ultra-orphan technologies. The challenge to payers lies with the value of the new technology and who is judging that value. Rising costs of orphan and ultra-orphan technologies will have more impact on market access in the future; over time there will be increasing resistance to high prices.